

Appl. No. 09/898,754  
Amd dated January 22, 2004  
Reply to Office Action of October 22, 2003

### **REMARKS**

This amendment is responsive to the Office Action dated October 22, 2003. Applicant has amended claim 8 to correct a typographical error and claim 15 to change "the message" to "the return communication." The amendment to claim 15 is made for clarity. Claims 10-14 and 21-73 have been withdrawn. Claims 74-79 are new. Claims 1-9 and 15-20 and 74-79 are pending.

### **Restriction Under 37 C.F.R. § 1.142(b)**

As noted above, claims 10-14 and 21-73 have been withdrawn pursuant to 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

### **Claim Rejections Under 35 U.S.C. § 102**

In the Office Action, the Examiner rejected claims 1-3, 7 and 15-17 under 35 U.S.C. § 102(b) as being anticipated by Morgan et al. (U.S. Pat. No. 5,593,426). The Examiner further rejected claims 1-4 and 15-18 under 35 U.S.C. § 102(a), saying that claims 1-4 and 15-18 are anticipated by Applicants' own admission.

### ***Rejections Based Upon Applicants' Disclosure***

Applicant respectfully traverses the rejections premised upon the Examiner's assertion that Applicants' own specification describes a conventional system that meets the limitations of the claims. This ground for rejection is without merit.

Applicants' FIG. 1, labeled as "Prior Art," discloses a medical device communication system that includes a medical device 11, a communication network 12 and a remote monitoring service 13. FIG. 1 does not disclose the other limitations of claims 1-4 or 15-18, however.

In particular, claims 1-4 are directed to a communication system, with claim 1 being independent and claims 2-4 being dependent directly or indirectly upon claim 1. Claims 1-4 recite "wherein the remote monitoring service is configured to send a communication to the medical device using the two-way communication network, the communication including an instruction for the medical device to perform a status

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assessment of at least one medical device parameter when the medical device is not in use, and wherein, in response to receiving the communication, the medical device is configured to obtain status assessment information and send a return communication back to the remote monitoring service using the two-way communication network, the return communication including the status assessment."

Page 3, lines 1-9 of Applicants' disclosure say:

The conventional remote monitoring service 13 is generally configured to obtain status information from the medical device 11. However, the remote monitoring service 13 is typically limited to implementing specific functions dependent on the use state of the medical device 11. For example, when the medical device 11 is powered, but not in operation, the medical device can provide self-test, calibration, expiration or maintenance information to the remote monitoring system. When the medical device 11 is in operation, the remote monitoring service 13 can send control information or the medical device 11 can provide patient diagnostic information to the remote monitoring system 13. (emphasis supplied)

Neither FIG. 1 nor pages 2-3 of Applicants' disclosure describe a conventional system as having a remote monitoring service that is configured to send a communication to the medical device using the two-way communication network, the communication including an instruction for the medical device to perform a status assessment of at least one medical device parameter when the medical device is not in use, as recited in claims 1-4. Further, neither FIG. 1 nor pages 2-3 of Applicants' disclosure describe a conventional system as having the medical device that, in response to receiving the communication, is configured to obtain status assessment information and send a return communication back to the remote monitoring service using the two-way communication network, the return communication including the status assessment, as recited in claims 1-4.

On the contrary, FIG. 1 does not disclose the nature of the communication between medical device 11 and remote monitoring service 13. FIG. 1 does not disclose elements recited in claims 1-4. In particular, FIG. 1 does not disclose that remote monitoring service 13 is configured to send a communication to medical device 11, the communication including an instruction for medical device 11 to perform a status

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assessment of at least one medical device parameter when medical device 11 is not in use. Similarly, FIG. 1 does not disclose that medical device 11 is configured to obtain status assessment information in response to the communication and is further configured to send a return communication back to remote monitoring service 13, the return communication including the status assessment.

Pages 2-3 of Applicants' description likewise fail to set forth these elements of claims 1-4. In particular, page 3 of Applicants' description states that remote monitoring service 13 is typically limited to implementing specific functions dependent on the use state of the medical device 11. Pages 2-3 of Applicants' description do not include a description of remote monitoring service 13 sending a communication to medical device 11, the communication including an instruction for medical device 11 to perform a status assessment of at least one medical device parameter when medical device 11 is not in use. Similarly, pages 2-3 of Applicants' description do not include a description of medical device 11 obtaining status assessment information in response to the communication and sending a return communication back to remote monitoring service 13, the return communication including the status assessment.

A similar analysis applies to claims 15-18, which recite a method for a remote monitoring service to communicate with a medical device using a two-way communication network. Claim 15 is independent, and claims 16-18 are dependent directly or indirectly upon claim 15. Claims 15-18 recite, among other things, "initiating a communication from the remote monitoring service to the medical device using the two-way communication network, the communication including an instruction by the remote monitoring service for the medical device to perform a status assessment of at least one medical device parameter when the medical device is not in use" and "sending a return communication from the medical device to the remote monitoring service using the two-way communication network, the return communication including the requested status assessment." As discussed above, these elements are not disclosed in Applicants' FIG. 1 nor on pages 2-3 of Applicants' specification.

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The Examiner's rejection of claims 1-4 and 15-18 under 35 U.S.C. § 102(a), based upon the assertion that claims 1-4 and 15-18 are anticipated by Applicants' own admission, is without basis and should be withdrawn.

***Rejections Based Upon Morgan et al.***

Applicant respectfully traverses the rejections based upon Morgan et al. Morgan et al. fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provide no teaching that would have suggested the desirability of modification to include such features.

The Applicants note at the outset that the Examiner failed to provide any analysis of Morgan et al. as that reference applies to claims 1-3, 7 and 15-17. The Examiner merely stated that claims 1-3, 7 and 15-17 are clearly anticipated by Morgan et al. The "clearly anticipated" remark represents the entirety of the Examiner's decision. The Examiner failed to specify, for example, where Morgan et al. disclose each and every feature of the claimed invention.

Applicants are entitled, as a matter of law, to a "full and reasoned explanation" of an agency's decision. The Examiner must provide not only a sound decision, but must also have articulated the reasons for that decision. In re Lee, 61 USPQ2d 1430, 1432-33 (Fed. Cir. 2002). The Examiner's rejection is improper under the principles of In re Lee. Applicants are left to guess at what portions of Morgan et al. were deemed relevant by the Examiner and Applicants are left to guess at what the Examiner's reasoning may have been. The rejection of claims 1-3, 7 and 15-17 should be withdrawn and should only be asserted if the Examiner can provide a "full and reasoned explanation" supporting it.

Furthermore, Morgan et al. do not clearly anticipate the invention as recited in claims 1-3, 7 and 15-17. In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must disclose each and every element of a claim. E.g., Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1579, 1599 (Fed. Cir. 2002). This well-known rule of law is commonly referred to as the "all-elements rule." If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(b) is improper.

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For example, Morgan et al. disclose no remote monitoring service, as recited in claims 1-3 and 7, and the Examiner has not identified any element in Morgan et al. that corresponds to a remote monitoring service. Morgan et al. also fail to disclose any element that is configured to send a communication to the medical device using a two-way communication network, "the communication including an instruction for the medical device to perform a status assessment of at least one medical device parameter when the medical device is not in use," as recited in claim 1-3 and 7.

Similarly, Morgan et al. also fail to disclose a method that includes initiating a communication from a remote monitoring service to a medical device using a two-way communication network, the communication including an instruction by the remote monitoring service for the medical device to perform a status assessment of at least one medical device parameter when the medical device is not in use, as recited in claims 15-17.

Because the Examiner has not established a prima facie case of anticipation under 35 U.S.C § 102, the rejections of claims 1-4, 7 and 15-18 should be withdrawn. Claims 1-4, 7 and 15-18 are in condition for allowance.

#### **Claim Rejections Under 35 U.S.C. § 103**

In the Office Action, the Examiner rejected claims 4 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Morgan et al. The Examiner further rejected claims 5, 6, 8 and 18-20 under 35 U.S.C. § 103(a) as being unpatentable over Morgan et al. Applicant respectfully traverses the rejections.

Claims 4-6 and 8-9 depend, directly or indirectly, upon claim 1. Because claim 1 is in condition for allowance, claims 4-6 and 8-9 are in condition for allowance as well.

Similarly, claims 18-20 depend, directly or indirectly, upon claim 15. Because claim 15 is in condition for allowance, claims 18-20 are in condition for allowance as well.

Furthermore, the Examiner has failed to make a prima facie case of obviousness.

In regard to claim 4, the Examiner asserted that Morgan et al. discloses a specialized mobile radio network, namely, RF signal carriers and a cellular telephone

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links. Nothing in the record supports the Examiner's conclusion that RF signal carriers and a cellular telephone links are a "specialized mobile radio network." On the contrary, these communication media are very general, and are capable of communicating a wide variety of information. The Examiner's interpretation of "specialized mobile radio network" is inconsistent with the plain meaning of the words. Moreover, Applicants' application distinguishes RF signal carriers and a cellular telephone links from a "specialized" network. See page 8 of Applicants' application, which mentions cellular systems and specialized systems as distinct systems.

In the alternative, the Examiner based the rejection of claim 4 upon the Examiner's own belief that it would have been obvious to one having ordinary skill in the art to modify the system taught by Morgan et al. to include a specialized mobile radio network. As a matter of law, the Examiner's own belief is not evidence that can support a prima facie case. If there are deficiencies in the evidentiary record, the deficiencies cannot be cured by general conclusions such as "general knowledge" or "common sense." In re Lee, 61 USPQ2d at 1434 (findings pertaining to obviousness must be based upon evidence in the record, not upon the subjective belief of the Examiner); see also In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (the Examiner's conclusory statements are not evidence).

Similar deficiencies apply to the Examiner's rejections of claims 5-6, 8-9 and 18-20. The Examiner's rejections of those claims is based upon the Examiner's subjective belief, which is not evidence that can support a rejection based upon obviousness.

Furthermore, the Examiner's rejection of claims 5-6, 8, and 18-20 are based in part upon the Examiner's assertion that the system of Morgan et al. could be modified to include networks as recited in claims 5-6, 8, and 18-20 as "an obvious matter of design choice." This assertion is incorrect for several reasons. First, it applies an incorrect legal standard. In a proper obviousness determination, the prior art must give a reason or motivation for making the claimed invention. E.g., In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995); In re Oetiker, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992). The combination of elements from non-analogous sources, in a manner that reconstructs the Applicants' invention only with the benefit of hindsight, is insufficient to support a prima

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facie case of obviousness. In re Oetiker, 24 USPQ2d at 1446. Where the prior art does not teach that references be combined to produce the claimed invention, the Examiner cannot cure this deficiency by using the words "design choice." In re Chu, 36 USPQ2d at 1094-95.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 4-6, 8-9 and 18-20 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

**New Claims:**

Applicants have added claims 74-79. Claims 74-76 are similar to claim 15, but recite a method as performed by a remote monitoring service. Claims 77-79 are similar to claim 15, but recite a method as performed by a medical device.

**CONCLUSION**

All claims in this application are in condition for allowance. Applicants respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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